



## Summary of Studies Supporting USDA Product Licensure

|   |   |
|---|---|
| Establishment Name  | Zoetis Inc.   |
| USDA Vet Biologics Establishment Number                                   | 190   |
| Product Code  | 48R5.21   |
| True Name   | Encephalomyelitis-Rabies-West Nile Virus Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | CORE EQ INNOVATOR - No distributor specified  |
| Date of Compilation Summary   | August 15, 2018   |

**Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.**

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|--|--|
| <b>Study Type</b>                        | Efficacy   |
| <b>Pertaining to</b>                     | Tetanus Toxoid   |
| <b>Study Purpose</b>                     | Efficacy against <i>Clostridium tetani</i>   |
| <b>Product Administration</b>            | Each product serial is tested in accordance with 9 CFR 113.114 requirements  |
| <b>Study Animals</b>                     | Guinea pigs  |
| <b>Challenge Description</b>             | NA   |
| <b>Interval observed after challenge</b> | NA   |
| <b>Results</b>                           | Efficacy requirements were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance per 9 CFR 113.114. |
| <b>USDA Approval Date</b>                | NA   |

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|--|--|
| <b>Study Type</b>                        | Efficacy   |
| <b>Pertaining to</b>                     | Eastern Equine Encephalomyelitis Virus (EEE)   |
| <b>Study Purpose</b>                     | Efficacy against EEE   |
| <b>Product Administration</b>            | Each product serial is tested in accordance with 9 CFR 113.207(b)(2) requirements  |
| <b>Study Animals</b>                     | Guinea pigs  |
| <b>Challenge Description</b>             | NA   |
| <b>Interval observed after challenge</b> | NA   |
| <b>Results</b>                           | Efficacy requirements were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance per 9 CFR 113.207(b)(2). |
| <b>USDA Approval Date</b>                | NA   |

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|--|--|
| <b>Study Type</b>                        | Efficacy   |
| <b>Pertaining to</b>                     | Western Equine Encephalomyelitis Virus (WEE)   |
| <b>Study Purpose</b>                     | Efficacy against WEE   |
| <b>Product Administration</b>            | Each product serial is tested in accordance with 9 CFR 113.207(b)(2) requirements  |
| <b>Study Animals</b>                     | Guinea pigs  |
| <b>Challenge Description</b>             | NA   |
| <b>Interval observed after challenge</b> | NA   |
| <b>Results</b>                           | Efficacy requirements were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance per 9 CFR 113.207(b)(2). |
| <b>USDA Approval Date</b>                | NA   |

| Study Type                        | Efficacy   |           |                         |      |                                    |  |                                    |                          |   |                         |   |          |   |      |   |      |   |                    |   |     |    |      |    |
|-----------------------------------|--|-----------|-------------------------|------|------------------------------------|--|------------------------------------|--------------------------|---|-------------------------|---|----------|---|------|---|------|---|--------------------|---|-----|----|------|----|
| Pertaining to                     | Rabies Virus (RV)  |           |                         |      |                                    |  |                                    |                          |   |                         |   |          |   |      |   |      |   |                    |   |     |    |      |    |
| Study Purpose                     | To demonstrate effectiveness and duration of immunity against rabies disease   |           |                         |      |                                    |  |                                    |                          |   |                         |   |          |   |      |   |      |   |                    |   |     |    |      |    |
| Product Administration            | Control Group: A single dose of a commercially licensed serial (LVP), West Nile Virus Vaccine, Eastern & Western & Venezuelan, Killed Virus, Tetanus Toxoid, West Nile Innovator® VEWT.<br>Vaccinate Group: A single dose of the experimental vaccine (IVP) was administered followed by a second vaccination 3-4 weeks later with the LVP.<br>All vaccines were administered by the intramuscular route.  |           |                         |      |                                    |  |                                    |                          |   |                         |   |          |   |      |   |      |   |                    |   |     |    |      |    |
| Study Animals                     | Thirty-nine 3 month old crossbred horses that were rabies sero-negative  |           |                         |      |                                    |  |                                    |                          |   |                         |   |          |   |      |   |      |   |                    |   |     |    |      |    |
| Challenge Description             | Challenged 14 months after initial vaccination with RV   |           |                         |      |                                    |  |                                    |                          |   |                         |   |          |   |      |   |      |   |                    |   |     |    |      |    |
| Interval observed after challenge | Horses were observed for 90 days post-challenge for clinical signs.  |           |                         |      |                                    |  |                                    |                          |   |                         |   |          |   |      |   |      |   |                    |   |     |    |      |    |
| Results                           | <p>An animal was classified as affected if it had any clinical sign post challenge and/or was positive by direct flouresent antibody (dFA) in the brain stem tissue. Clinical signs included: depression, nervousness, restless, walking in circles, hyperresponse (auditory and visual stimuli), disorientation, seizures, salivation, labored breathing, death and other clinical signs.</p> <p><b><u>Table 1. Number of Animals Affected by Rabies Virus</u></b></p> <table><tr><th rowspan="2">Treatment</th><th colspan="4">Disease</th><th rowspan="2">Total Animals Challenged Per Group</th></tr><tr><th>YES<br/>No. of<br/>Animals</th><th>%</th><th>NO<br/>No. of<br/>Animals</th><th>%</th></tr><tr><td>Controls</td><td>4</td><td>80.0</td><td>1</td><td>20.0</td><td>5</td></tr><tr><td>Vaccinated Animals</td><td>2</td><td>7.4</td><td>25</td><td>92.6</td><td>27</td></tr></table> <p>The requirements of 9 CFR 113.209 were met.</p> <p>The raw data is shown on the attached page.</p> | Treatment | Disease                 |      |                                    |  | Total Animals Challenged Per Group | YES<br>No. of<br>Animals | % | NO<br>No. of<br>Animals | % | Controls | 4 | 80.0 | 1 | 20.0 | 5 | Vaccinated Animals | 2 | 7.4 | 25 | 92.6 | 27 |
| Treatment                         | Disease  |           |                         |      | Total Animals Challenged Per Group |  |                                    |                          |   |                         |   |          |   |      |   |      |   |                    |   |     |    |      |    |
|                                   | YES<br>No. of<br>Animals   | %         | NO<br>No. of<br>Animals | %    |                                    |  |                                    |                          |   |                         |   |          |   |      |   |      |   |                    |   |     |    |      |    |
| Controls                          | 4  | 80.0      | 1                       | 20.0 | 5                                  |  |                                    |                          |   |                         |   |          |   |      |   |      |   |                    |   |     |    |      |    |
| Vaccinated Animals                | 2  | 7.4       | 25                      | 92.6 | 27                                 |  |                                    |                          |   |                         |   |          |   |      |   |      |   |                    |   |     |    |      |    |
| USDA Approval Date                | November 05, 2014  |           |                         |      |                                    |  |                                    |                          |   |                         |   |          |   |      |   |      |   |                    |   |     |    |      |    |

### Individual Animal Data:

| <b>Treatment</b>  | <b>Animal</b> | <b>At Least 1 Clinical Sign?</b> | <b>dFA<sup>(1)</sup> Result</b> | <b>Affected? <sup>(2)</sup></b> |
|---|---------------|----------------------------------|---------------------------------|---------------------------------|
| Control   | 076 538 122   | YES                              | Positive                        | YES                             |
|   | 076 880 039   | YES                              | Positive                        | YES                             |
|   | 076 880 526   | YES                              | Positive                        | YES                             |
|   | 076 881 102   | YES                              | Positive                        | YES                             |
|   | 076 887 310   | NO                               | Negative                        | NO                              |
|   |               |                                  |                                 |                                 |
| Vaccinated  | 076 513 039   | NO                               | Negative                        | NO                              |
|   | 076 517 279   | NO                               | Negative                        | NO                              |
|   | 076 519 794   | NO                               | Negative                        | NO                              |
|   | 076 523 267   | NO                               | Negative                        | NO                              |
|   | 076 523 775   | NO                               | Negative                        | NO                              |
|   | 076 527 858   | YES                              | Positive                        | YES                             |
|   | 076 539 080   | NO                               | Negative                        | NO                              |
|   | 076 543 085   | NO                               | Negative                        | NO                              |
|   | 076 549 351   | NO                               | Negative                        | NO                              |
|   | 076 551 273   | NO                               | Negative                        | NO                              |
|   | 076 555 803   | NO                               | Negative                        | NO                              |
|   | 076 558 785   | NO                               | Negative                        | NO                              |
|   | 076 560 848   | NO                               | Negative                        | NO                              |
|   | 076 561 127   | NO                               | Negative                        | NO                              |
|   | 076 872 322   | NO                               | Negative                        | NO                              |
|   | 076 874 029   | YES                              | Positive                        | YES                             |
|   | 076 877 314   | NO                               | Negative                        | NO                              |
|   | 076 881 010   | NO                               | Negative                        | NO                              |
|   | 076 881 514   | NO                               | Negative                        | NO                              |
|   | 076 886 366   | NO                               | Negative                        | NO                              |
|   | 077 001 331   | NO                               | Negative                        | NO                              |
|   | 077 004 324   | NO                               | Negative                        | NO                              |
|   | 077 008 099   | NO                               | Negative                        | NO                              |
|   | 077 010 273   | NO                               | Negative                        | NO                              |
|   | 077 012 045   | NO                               | Negative                        | NO                              |
|   | 077 013 830   | NO                               | Negative                        | NO                              |
|   | 077 014 833   | NO                               | Negative                        | NO                              |
| (1) dFA = Direct Fluorescent Antibody Test                                      |               |                                  |                                 |                                 |
| (2) YES = Positive by dFA in Brain or at least one clinical sign post challenge |               |                                  |                                 |                                 |
| NO = Negative by dFA in brain or at least one clinical sign post challenge      |               |                                  |                                 |                                 |

| <b>Study Type</b>                        | Efficacy   |                 |   |            |      |          |      |
|--|--|-----------------|---|------------|------|----------|------|
| <b>Pertaining to</b>                     | West Nile Virus (WNV)  |                 |   |            |      |          |      |
| <b>Study Purpose</b>                     | To demonstrate effectiveness and duration of immunity against WNV  |                 |   |            |      |          |      |
| <b>Product Administration</b>            | Two doses, administered intramuscularly 3 weeks apart  |                 |   |            |      |          |      |
| <b>Study Animals</b>                     | Thirty-two, 9-11 month (at vaccination) old mixed breed horses that were WNV sero-negative: 19 vaccinates, 11 controls (3 added at challenge)  |                 |   |            |      |          |      |
| <b>Challenge Description</b>             | Challenged 12 months after vaccination with WNV  |                 |   |            |      |          |      |
| <b>Interval observed after challenge</b> | After challenge, animals were monitored twice daily for 14 days, and then once daily for an additional week  |                 |   |            |      |          |      |
| <b>Results</b>                           | <p>The primary outcome was prevention of WNV viremia. Serum samples were collected from each animal twice daily from challenge for 2 weeks, and once thereafter.</p> <p>Table 1. Viremia detected in vaccinated and control horses after experimental challenge with West Nile Virus</p> <table border="1"> <thead> <tr> <th>Treatment group</th><th>Number of viremic horses/horses challenged horses</th></tr> </thead> <tbody> <tr> <td>Vaccinates</td><td>1/19</td></tr> <tr> <td>Controls</td><td>9/11</td></tr> </tbody> </table> <p>The raw data is shown on the attached page.</p> | Treatment group | Number of viremic horses/horses challenged horses | Vaccinates | 1/19 | Controls | 9/11 |
| Treatment group                          | Number of viremic horses/horses challenged horses  |                 |   |            |      |          |      |
| Vaccinates                               | 1/19   |                 |   |            |      |          |      |
| Controls                                 | 9/11   |                 |   |            |      |          |      |
| <b>USDA Approval Date</b>                | August 13, 2002  |                 |   |            |      |          |      |

**Table 2: Number of Viremia incidences detected in vaccinated and control horses after experimental challenge with West Nile virus (WNV)**

| ID number             | Group      | Days Post Challenge |     |     |     |     |     |     |     |     |     |
|-----------------------|------------|---------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|
|                       |            | 0                   | 0.5 | 1.0 | 1.5 | 2.0 | 2.5 | 3.0 | 3.5 | 4.0 | 4.5 |
| 4271041A29            | Controls   | -                   | -   | -   | -   | -   | +   | -   | +   | -   | -   |
| 4273363D4C            |            | -                   | -   | +   | +   | -   | +   | +   | +   | +   | +   |
| 422C651E1C            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | +   |
| 524A3B6477/5317501016 |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | +   |
| 421B355400/53190B764A |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | +   |
| 42735D5E73            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421A056A0A            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421E51781D            |            | -                   | -   | -   | -   | +   | -   | +   | +   | +   | -   |
| 421E4F723F            |            | -                   | -   | -   | -   | -   | +   | -   | +   | +   | +   |
| 421B2C3C13            |            | -                   | -   | +   | -   | -   | +   | +   | +   | +   | -   |
| 421E565A55            |            | -                   | -   | -   | -   | +   | -   | +   | +   | -   | -   |
| 421A002D66            | Vaccinates | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 5308581947            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 422C63576B            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 417B242E4D            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 422C301B30            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 422C643F28            |            | -                   | -   | -   | -   | -   | +   | -   | -   | -   | -   |
| 421E77405A            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421E712746            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421E78465C            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421E5C0856            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421E6C706F            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 422C74131B            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 52491F2C40            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 422C63330B            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421945065E            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 422C5A5E36            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421E606E22            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421E5B025B            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421E6A2314            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |

+ Positive for WNV

- Negative for WNV



**Table 2 (continued)**

| ID number             | Group      | Days Post Challenge |     |     |     |     |     |     |     |     |     |
|-----------------------|------------|---------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|
|                       |            | 5.0                 | 5.5 | 6.0 | 6.5 | 7.0 | 7.5 | 8.0 | 8.5 | 9.0 | 9.5 |
| 4271041A29            | Controls   | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 4273363D4C            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 422C651E1C            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 524A3B6477/5317501016 |            |                     | +   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421B355400/53190B764A |            | +                   | +   | -   | -   | -   | -   | -   | -   | -   | -   |
| 42735D5E73            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421A056A0A            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421E51781D            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421E4F723F            |            | -                   | +   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421B2C3C13            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421E565A55            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421A002D66            | Vaccinates | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 5308581947            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 422C63576B            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 417B242E4D            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 422C301B30            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 422C643F28            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421E77405A            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421E712746            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421E78465C            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421E5C0856            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421E6C706F            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 422C74131B            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 52491F2C40            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 422C63330B            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421945065E            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 422C5A5E36            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421E606E22            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421E5B025B            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |
| 421E6A2314            |            | -                   | -   | -   | -   | -   | -   | -   | -   | -   | -   |

+ Positive for WNV

- Negative for WNV

**Table 2 (continued)**

| ID number             | Group      | Days Post Challenge |      |      |      |      |      |      |      |      |      | 21.0 |
|-----------------------|------------|---------------------|------|------|------|------|------|------|------|------|------|------|
|                       |            | 10.0                | 10.5 | 11.0 | 11.5 | 12.0 | 12.5 | 13.0 | 13.5 | 14.0 | 14.5 |      |
| 4271041A29            | Controls   | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 4273363D4C            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 422C651E1C            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 524A3B6477/5317501016 |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 421B355400/53190B764A |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 42735D5E73            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 421A056A0A            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 421E51781D            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 421E4F723F            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 421B2C3C13            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 421E565A55            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 421A002D66            | Vaccinates | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 5308581947            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 422C63576B            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 417B242E4D            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 422C301B30            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 422C643F28            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 421E77405A            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 421E712746            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 421E78465C            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 421E5C0856            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 421E6C706F            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 422C74131B            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 52491F2C40            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 422C63330B            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 421945065E            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 422C5A5E36            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 421E606E22            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 421E5B025B            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |
| 421E6A2314            |            | -                   | -    | -    | -    | -    | -    | -    | -    | -    | -    | -    |

+ Positive for WNV  
- Negative for WNV

|                                     |   |                         |                         |  |                                 |
|-------------------------------------|---|-------------------------|-------------------------|--|---------------------------------|
| Study Type                          | Safety  |                         |                         |  |                                 |
| Pertaining to                       | ALL   |                         |                         |  |                                 |
| Study Purpose                       | Demonstrate safety of product under typical use conditions  |                         |                         |  |                                 |
| Product Administration              | Horses were administered a vaccination series consisting of a single dose of experimental serial (IVP) followed 3-4 weeks later with a single dose of a commercially licensed serial (LVP), West Nile Virus Vaccine, Eastern & Western & Venezuelan, Killed Virus, Tetanus Toxoid, West Nile Innovator® VEWT. Vaccination was given by the intramuscular route. |                         |                         |  |                                 |
| Study Animals                       | Six hundred eighty two mixed breed client owned horses; 209 were ≤ 3 months of age and 473 were ≥ 4 months of age   |                         |                         |  |                                 |
| Challenge Description               | NA  |                         |                         |  |                                 |
| Interval observed after vaccination | Horses were observed for abnormal health events a minimum of 21 days after each vaccination.  |                         |                         |  |                                 |
| Results                             | Table 1: Frequency distribution of abnormal health events after vaccination.  |                         |                         |  |                                 |
|                                     | Number of Vaccinations  | 1 <sup>st</sup> Vac IVP | 2 <sup>nd</sup> Vac LVP | Abnormal Health Event                      | Number of Horses/% Vaccinations |
|                                     | 1359<br>Vaccinations<br>(682 doses of IVP, 677 doses of LVP)  |                         | 1                       | Ataxia                                     | 1 (0.15%)                       |
|                                     |   | 1                       |                         | Cough                                      | 1 (0.15%)                       |
|                                     |   |                         | 1                       | Fever                                      | 1 (0.15%)                       |
|                                     |   |                         | 1                       | Hoof Abscess Left Front/Left Hind Lameness | 1 (0.15%)                       |
|                                     |   | 1*                      |                         | Injection Site Swelling (1.5-5cm)          | 1 (0.15%)                       |
|                                     |   | 4                       |                         | Lameness                                   | 4 (0.59%)                       |
|                                     |   | 1*                      |                         | Muscle Pain                                | 1 (0.15%)                       |
|                                     |   | 1                       |                         | Nasal Discharge                            | 1 (0.15%)                       |
|                                     |   | 1                       | 1                       | NOS  | 2 (0.29%)                       |
|                                     |   | 2                       |                         | Skin Haematoma                             | 2 (0.29%)                       |
|                                     |   | 2                       | 3                       | Skin Lesion NOS**                          | 4 (0.59%)                       |
|                                     |   | 2                       | 1                       | Skin Oedema                                | 3 (0.44%)                       |
|                                     |   | 1                       | 1                       | Ataxia                                     | 2 (0.29%)                       |
|                                     |   | 1                       |                         | Blepharoedema                              | 1 (0.15%)                       |
|                                     |   | 2                       |                         | Cough                                      | 2 (0.29%)                       |
|                                     |   |                         | 1                       | Depression                                 | 1 (0.15%)                       |
|                                     |   |                         | 1                       | Diarrhoea                                  | 1 (0.15%)                       |
|                                     |   |                         | 3                       | Fever                                      | 3 (0.44%)                       |
|                                     |   | 4                       | 3                       | Lameness                                   | 7 (1.03%)                       |
|                                     |   |                         | 1                       | Leukocytosis                               | 1 (0.15%)                       |
|                                     |   | 2                       | 1                       | Nasal Discharge                            | 3 (0.44%)                       |
|                                     |   |                         | 1                       | NOS  | 1 (0.15%)                       |
|                                     |   |                         | 2                       | Skin Lesion NOS                            | 2 (0.29%)                       |
|                                     |   |                         | 1                       | Skin Oedema                                | 1 (0.15%)                       |

|                           |  |
|---------------------------|--|
|                           | <p>NOS = Not Otherwise Specified</p> <p>*Attributed to Vaccination by licensee. Swelling resolved within 24 hours.</p> <p>**One horse was recorded with 2 separate abnormal health events both described as Skin Lesion, NOS</p> |
| <b>USDA Approval Date</b> | May 13, 2016   |

|   |  |                            |                           |                       |                                 |
|---|--|----------------------------|---------------------------|-----------------------|---------------------------------|
| Study Type  | Safety   |                            |                           |                       |                                 |
| Pertaining to   | ALL  |                            |                           |                       |                                 |
| Study Purpose   | Demonstrate safety of product under typical use conditions   |                            |                           |                       |                                 |
| Product Administration  | Horses were administered a vaccination series consisting of a single dose of experimental serial (IVP) followed 3-4 weeks later with a single dose of commercial serial (LVP), West Nile Virus Vaccine, Eastern & Western & Venezuelan, Killed Virus, Tetanus Toxoid, West Nile Innovator® VEWT. Vaccination was given by intramuscular route. |                            |                           |                       |                                 |
| Study Animals   | Three hundred and twenty five mixed breed client owned horses; 112 were ≤ 3 months of age and 213 were ≥ 4 months of age   |                            |                           |                       |                                 |
| Challenge Description   | NA   |                            |                           |                       |                                 |
| Interval observed after vaccination   | Horses were observed for abnormal health events a minimum of 21 days after each vaccination.   |                            |                           |                       |                                 |
| Results   | Table 1: Frequency distribution of abnormal health events after vaccination  |                            |                           |                       |                                 |
|   | Treatment / Number of Vaccinations   | 1 <sup>st</sup> Vac. (IVP) | 2 <sup>nd</sup> Vac (LVP) | Abnormal Health Event | Number of Horses/% Vaccinations |
|   | 325 Vaccinations at each time point  | 1 *                        |                           | Abdominal Pain        | 1 (0.15%)                       |
|   |  |                            | 1 *                       | Abortion              | 1 (0.15%)                       |
|   |  | 3                          |                           | Lameness              | 3 (0.46)                        |
|   |  | 1                          |                           | Wheals                | 1 (0.15)                        |
| * These events occurred in the same horse. Affirmed by licensee to have a cause other than vaccination. |  |                            |                           |                       |                                 |
| USDA Approval Date  | January 3, 2018  |                            |                           |                       |                                 |